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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,554	10/04/2000	Annette Marian Doherty	5604-D1-01-TMC	1962

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/678,554	Doherty
Examiner	**Art Unit**
David Lukton	1653

-- Th MAILING DATE of this communication app ars on the cover she t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 19, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-25 is/are pending in the applica

4a) Of the above, claim(s) 15-18 and 20-23 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-14, 19, 24, and 25 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Pursuant to the directives of paper No. 7 (filed 11/19/01), claims 20-25 have been added. In addition, applicants have directed an amendment of claim 1. However, this amendment has not been entered, since the directive to amend the claim does not comply with rules that went into effect in March of 2001. In amending a claim, two copies are required, one of which shows the changes made.

Claims 15-18, 20-23 are withdrawn from consideration at this time. Claims 1-14, 19, 24-25 are examined in this Office action.

Applicants' arguments filed 11/19/01 have been considered and found persuasive in part. The rejection of claim 1 for its recitation of the terms "pharmaceutically" and "prodrugs" is withdrawn. However, the rejection of claim 19 is maintained, and is extended to claim 25.

*

The abstract is objected to. Line 2 of the abstract recites "formula I". However, as a grammatical matter, this should not be followed by a period. In addition, the second sentence of the abstract is indented so as to create the appearance of two separate paragraphs. An abstract, however, must be limited to just one paragraph. In addition, the last line of the abstract recites the following: "formula I..". Note that this is followed by two periods. However, only one period should be used.

*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

See, for example, the two sequences on page 52.

Applicants have argued that they are exempt from the requirement because no sequence appears in the claims. However, the fact that no sequence appears in the claims does not provide an exemption, as suggested by applicants. As to the fact that no sequence listing was required in the parent application, this does not provide "immunity" from the requirement.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of USP 6,265,382; claim 19 (instant application) is rejected over claim 13 of '382. Although the conflicting claims are not

identical, they are not patentably distinct from each other. Applicants have argued that, as a general proposition, it is improper for an examiner to impose a double patenting rejection until after all claims have been found allowable. However, applicants are incorrect on this point. The rejection is maintained.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As indicated previously, applicants have shown (pp. 52-56) that the compounds of examples 1-8 exhibit some propensity to inhibit ras farnesyl transferase *in vitro*. It is stipulated that the following claims are enabled:

> *A method of inhibiting ras farnesyl transferase in a mammal in need thereof comprising administering to said mammal a compound of claim 1 for a time and under conditions effective to inhibit ras farnesyl transferase.*
>
> *A method of inhibiting ras farnesyl transferase in a mammal afflicted with restenosis, cancer or psoriasis comprising administering to said mammal a compound of claim 1 for a time and under conditions effective to inhibit ras farnesyl transferase.*

However, claim 19 employs the term "pharmaceutical". This terms carries with it the implied assertion that the compounds can be used therapeutically. This would include treatment of cancer, restenosis and atherosclerosis. As indicated previously it is possible that the underlying biochemical processes can be inhibited. But the question is whether the degree of inhibition is sufficient to be of benefit. The degree to which farnesyl transferase will be inhibited *in vivo* by a particular compound cannot be predicted merely be viewing the structure of the compound. Indeed, applicants have encountered variability in the degree of inhibition *in vitro*; these results could not have been predicted merely by viewing structures of compounds. In addition, it is not established that the IC50 value of even the best inhibitor is sufficiently low to be effective in the treatment of a given disease in a mammal. Another question is that of the degree of criticality of the farnesyl transferase to the cell proliferation process. Even if e.g., 90% of the enzyme activity could be blocked, would that be sufficient? It is suggested that the terms "pharmaceutical" and be deleted from each of claims 19 and 25.

*

Claims 1-19, 19, 24-25 are are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 is drawn to "compounds" in the plural. However, applicants are claiming single compounds, rather than mixtures of compounds. Accordingly, the term "compound" should be used in the singular. Moreover, the dependent claims recite

"compound" in the singular. (To reiterate, the amendment of claim 1 has not been entered).

- The dependent claims recite "a compound". However, the definite article ("the") should be used instead, since the compounds that are referred to have already been identified.

- Claim 1 recites (last two lines):
  "and the pharmaceutically acceptable salts and prodrugs thereof".
  Thus, the question arises, are applicans claiming a mixture of compounds, salts of compounds and prodrugs of compounds? If so, the claim should be directed to a *mixture*. Otherwise, clarity would be enhanced by claiming *a compound* (in the singular) and reciting the following in the last two lines of the claim:
  ...or a pharmaceutically acceptable salt thereof, or a prodrug thereof.

- Claim 19 makes reference to a composition. However, a composition must have two components. Either or both of the following is suggested:
  A composition comprising a compound according to claim 1, and a carrier.

  A composition comprising a suitable carrier, and a compound according to claim 1 in an amount effective to inhibit ras farnesyl transferase.

- Claim 25 recites (last two lines): "for use a pharmaceutical". However, this renders the claim indefinite as to the objectives of the "pharmaceutical". For example, could the composition be used to treat multiple sclerosis, AIDS or Alzheimer's Disease?

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for the patent.

Claims 1, 2, 5, 7, 19 are rejected under 35 U.S.C. §102(e) as being anticipated by Bolton (USP 5,830,868).

Bolton discloses (col 19) compound # 26. This corresponds to applicants variables as follows:

Y = oxygen

R3 = substituted benzyl

R2 = $-CH_2-CH_2-C_6H_5$

Thus, the claims are anticipated.

No claim is allowed.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.